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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/701,515	11/06/2003	Said I. Hakky	MR2493-38	7376

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ELLICOTT CITY, MD 21043

EXAMINER

BOGART, MICHAEL G

ART UNIT	PAPER NUMBER
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3761

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/701,515

Applicant(s)

HAKKY ET AL.

Examiner

Michael G. Bogart

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 7-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 7-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Claim Rejections – 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

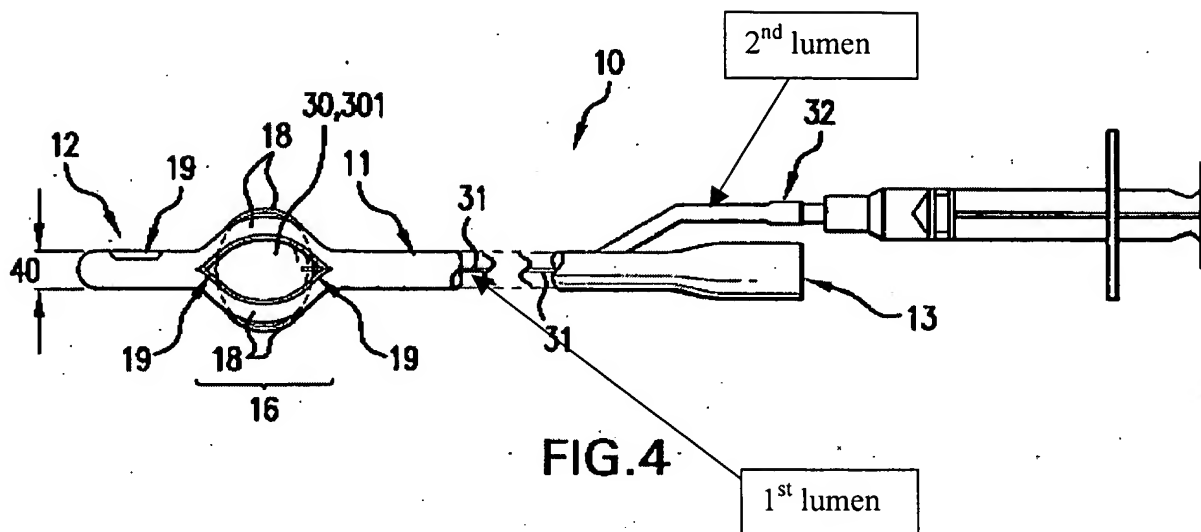
Claims 1, 2 and 7-12 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1 and 8 include the new limitation the tube slit portions are “devoid of separate spring members.” This is a negative limitation that defines the invention of what it is not, rather than pointing out the invention. The instant specification is silent as to the presence or absence of separate spring members. Any negative limitation or exclusionary proviso must have basis in the original disclosure. The mere absence of a positive recitation is not basis for an exclusion. MPEP § 2173.05(i).

Claim 9 includes the new limitation such that the flexible tube defines “only one single lumen.” This is a negative limitation that defines the invention of what it is not, rather than pointing out the invention. The instant figures show a V-shaped tube having a first and second lumen (see figure 4, *infra*). The instant specification does not expressly teach the absence of a second lumen. Any negative limitation or exclusionary proviso must have basis in the original

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disclosure. The mere absence of a positive recitation is not basis for an exclusion. MPEP § 2173.05(i).



Claims 2, 7 and 10-12 are rejected as being dependent parent claims that are rejected under 35 USC § 112(1).

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 1, 2, 7, 8 and 12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Spinosa *et al.* (US 3,815,608; hereinafter "Spinosa") in view of Termanini (US 4,154,242).

Regarding claim 1, Spinosa teaches a self-retaining urinary drainage catheter system (10), comprising:

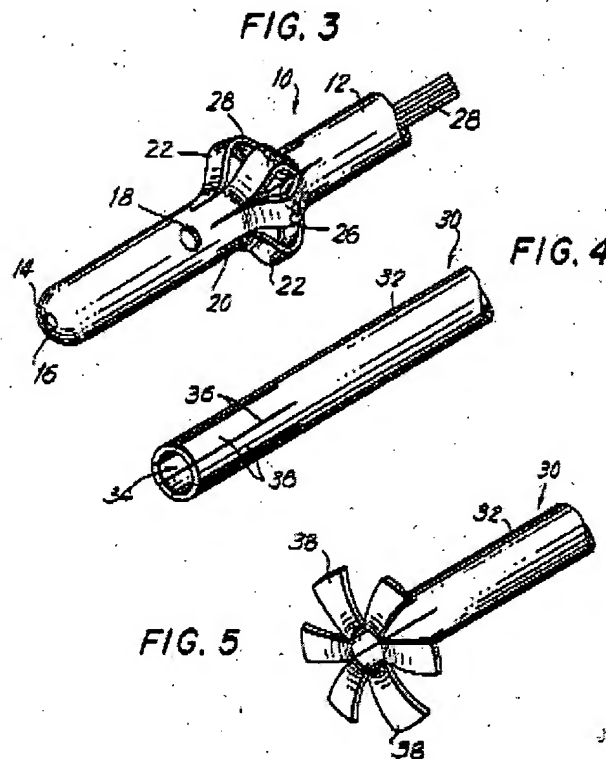
(a) a longitudinally extending flexible tube (12) having a predetermined outer diameter, an open distal end and a closed proximal end (14), said flexible tube (12) defining at least one lumen, said closed proximal end (14) having a plurality of longitudinally directed slits (20) formed through a wall of said flexible tube (12) defining a plurality of inherently resilient flexible tube (12) slit portions (22) devoid of separate spring members; and

(b) a reversibly and radially displaceable mechanism (28) being capable of displacing said plurality of flexible tube slit portions (22) of said proximal end (14) to a first configuration (fig. 3) abutting in a non-continuous manner an inner surface of a urinary bladder, said first configuration of flexible tube slit portions (22) having an outer diameter greater than said predetermined diameter of said flexible tube (12) and defining a plurality of drainage apertures (20), and being capable of displacing said plurality of flexible tube slit portions (22) to a second configuration (fig. 1) wherein said plurality of flexible tube slit portions (22) has a diameter substantially equal to said predetermined outer diameter of said flexible tube (12), said plurality of drainage apertures (20) being in direct fluid communication with said lumen, wherein said reversibly and radially displaceable mechanism (28) does not substantially obstruct a lumen of

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said catheter (10), and said catheter (10) is reversably insertable in a human being without using a stylet; and

(c) a wire control device (28) positionally located external and displaced from the longitudinally extending flexible tube (12), said wire control device (28) having a reversible locking mechanism (26, 28) capable of locking said wire control device (28) in a predetermined position (by hand for example)(col. 2, line 46-col. 3, line 37)(see figures 3-5, infra).



Regarding the functional limitations (e.g., reversibly insertable), apparatus claims must be structurally distinguishable from the prior art. MPEP § 2114.

Spinosa does not expressly teach that the catheter is sufficiently stiff enough to be inserted into a human without a stylet.

Termanini refers to Spinosa disclosing a catheter that is sufficiently stiff enough to be inserted into a human without a stylet (col. 1, line 58-col. 2, line 10).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to make the catheter of Spinosa sufficiently stiff as suggested by Termanini in order to provide a catheter that can be inserted without requiring additional accessories.

Regarding claims 2 and 8, Spinosa teaches that said a wire control device (28) is longitudinally and slidably positioned within a lumen of said longitudinally extending flexible tube (12), said wire control device (28) fixedly secured at a first end (26) to an inner surface of said closed proximal end (12, 14) and having a length greater than a length of said longitudinally extending flexible tube (12) so that a second end of said wire control device (28) protrudes through said open distal end (figures 3-5).

Regarding claim 7, Termanini teaches a wire control device (28) that is composed of a metal or non-metallic material (nylon, polypropylene)(column 4, lines 43-47).

Regarding claim 12, Termanini teaches that said wire control (28) device further comprises a means (48, 50) for reversibly locking said wire control device (28) in a predetermined position (see figures 1 & 2).

Claims 9-11 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Baskin (US 2,854,983) in view of Rosenberg (US 4,787,892).

Regarding claim 9, Baskin teaches a self-retaining urinary drainage catheter system (10), comprising:

(a) a longitudinally extending flexible tube (12, 30) having a predetermined outer diameter, an open distal end and a closed proximal end (34), said flexible tube (12, 30) defining

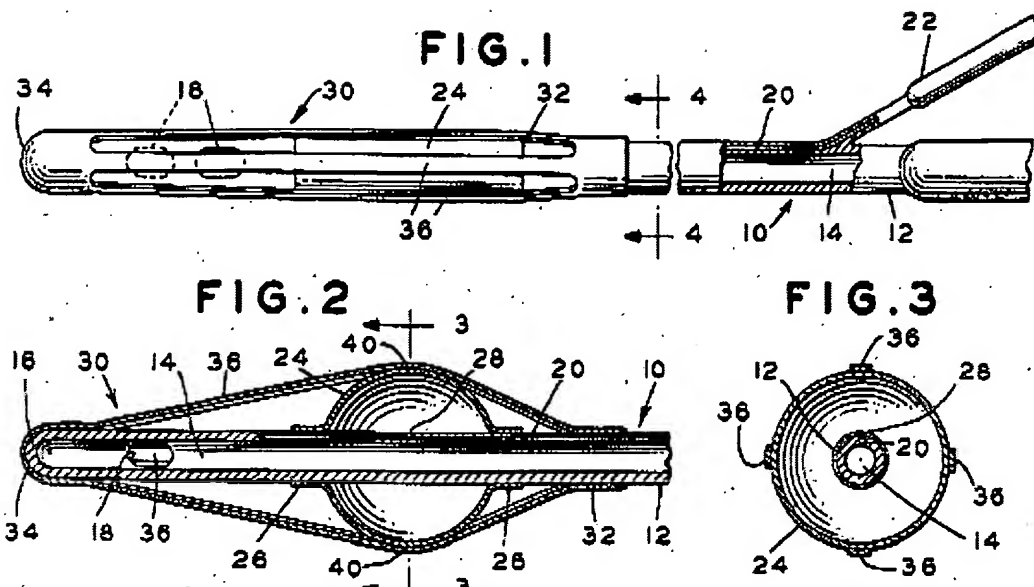
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at least one lumen (interior of tubular element (30)), said closed proximal end (34) having a plurality of longitudinally directed slits (36) formed through an outer wall of said flexible tube (12, 30) defining a plurality of flexible tube slit portions (36); and

(b) a reversably inflatable balloon (24) located between said plurality of flexible tube slit portions (36), a microcatheter (20), wherein a fluid may be reversably injected so as to expand said reversably inflatable balloon (24) for reversably and radially displacing said plurality of flexible tube slit portions (36) of said proximal end (34) to a first configuration abutting in a non-continuous manner an inner surface of a urinary bladder, said first configuration of flexible tube slit portions (36) having an outer diameter greater than said predetermined diameter of said flexible tube (12, 30) and defining a plurality of drainage apertures (36), and displacing said plurality of flexible tube slit portions (36) to a second configuration wherein said plurality of flexible tube slit portions (36) has a diameter substantially equal to said predetermined outer diameter of said flexible tube, said plurality of drainage apertures being in direct fluid communication with said lumen wherein said microcatheter (20) does not substantially obstruct a lumen of said catheter (10), and said catheter (10) being of sufficient stiffness to be reversably insertable in a human being without using a stylet (see figures 1 and 2, below).

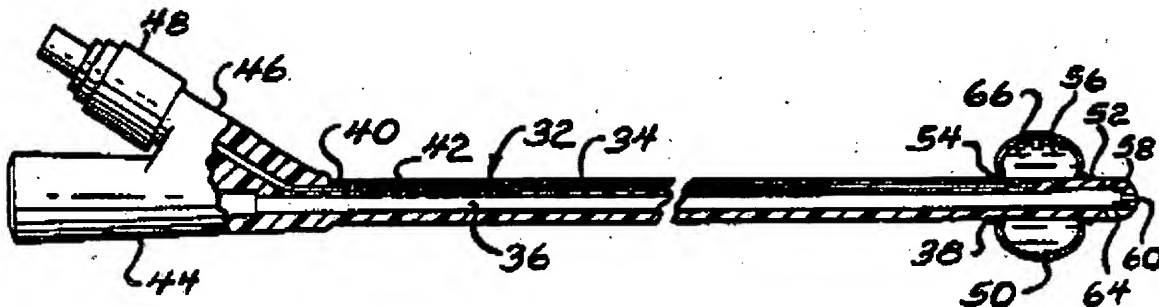
Regarding the functional limitations (e.g., reversibly insertable), apparatus claims must be structurally distinguishable from the prior art. MPEP § 2114. The device of Baskin could be at least be partially inserted into a sufficiently large diameter wound or human orifice without the aid of a stylet.

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Baskin does not expressly disclose a valve.

Rosenberg teaches a balloon catheter (32) having a balloon inflation tube (42) that controls fluid flow to the balloon via a valve (48)(see figure 6, below).



At the time of the invention, it would have been obvious to one of ordinary skill in the art to add the valve of Rosenberg to the fluid inflation tube of the catheter of Baskin in order to provide a means of keeping the balloon inflated.

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Regarding the new limitation such that the flexible tube defines only one lumen, this makes what is known in the art to be integral, separable, which by itself is not sufficient to patentably distinguish the invention over the prior art. See *In re Dulberg*, 289 F.2d 522, 523, 129 USPQ 348, 349 (CCPA 1961). MPEP § 2144.04.

Regarding claim 10, Baskin teaches a spherical balloon (24)(figure 2).

Regarding claim 11, Rosenberg teaches an oblong balloon (50)(figure 6).

Response to Arguments

Applicant's arguments with respect to claims 1, 2, 7, 8 and 12 have been considered but are moot in view of the new ground(s) of rejection.

Regarding claims 9-11, applicant's arguments filed 03 November 2006 have been fully considered but they are not persuasive.

Applicants assert that the new limitation such that the tube defines only a single limitation is not persuasive because making what is known in the prior art to be integral separable is not sufficient to patentably distinguish the claimed invention. See *In re Dulberg*, supra.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Bogart whose telephone number is (571) 272-4933.

In the event the examiner is not available, the Examiner's supervisor, Tatyana Zalukaeva may be reached at phone number (571) 272-1115. The fax phone number for the organization


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where this application or proceeding is assigned is (571) 273-8300 for formal communications.

For informal communications, the direct fax to the Examiner is (571) 273-4933.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-3700.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Michael Bogart
18 January 2007

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

